-continued

HCG concentration (U/liter)	Measured values (BIT)
3000	135

The test strip assembly shown here can also be achieved if the glucose oxidase and the anti-HCG antibody are located in the same zone. The test strip, which is correspondingly shorter, then renders the result after approx. 10 minutes.

We claim:

[1. An analytical device for the detection or determination of a component in a fluid wherein said component is an analyte with bioaffinity binding properties, comprising a layer of a plurality of substantially planar zones adjacent one another and in absorbent contact with one another, said layer including:

a mobile phase application zone (MPAZ), an intermediate zone (IZ) and an adsorption zone (AZ), liquid being capable of moving by adsorption from said MPAZ through said IZ to said AZ, and wherein said IZ further comprises a solid phase zone (SPZ) having at least one unlabelled reactant, capable of interactions of biological affinity with at least one analyte;

at least one unattached, labelled reactant (conjugate), capable of interactions of biological affinity with said at least one analyte, disposed in an area between the MPAZ and the SPZ; and

an analyte application zone disposed at said MPAZ or in between said MPAZ and said AZ, wherein after application of said at least one analyte, said at least one analyte is reacted with said reactants in said layer and is detected in said layer.]

[2. A device as claimed in claim 1, wherein the MPAZ has the function of a volume metering element and releases to the subsequent zones at least sufficient liquid for the liquid, controlled by capillary forces, to reach the end of the AZ.]

[3. A device as claimed in claim 1, wherein the MPAZ is a plastic sponge or a particulate layer which is composed of hydrophilic polymers and which is capable of containing chemicals, buffer substances or other substances required for certain tests.]

[4. A device as claimed in claim 1, wherein the analyte application zone retains blood cells.]

[5. A device as claimed in claim 1, wherein all or some of the reagents required for the detection of the labelling are present in one or more of substantially planar zones of the device.]

[6. A device as claimed in claim 1, wherein said at least one unlabelled reactant is fixed to said SPZ by means of covalent bonds.]

[7. A device as claimed in claim 1, wherein said at least one unlabelled reactant is fixed to said SPZ by means of absorption.]

[8. A device as claimed in claim 1, wherein said at least one unlabelled reactant is fixed to said SPZ by means of an interaction of biological affinity.]

[9. A device as claimed in claim 1, further including a plurality of solid phase zones (SPZs) for the detection of a plurality of analytes, said analytes including at least one attachment point of biological affinity, each of said SPZs being adjacent one another in said layer and each of said SPZs including said unlabelled reactants fixed thereto, said unlabelled reactants of each SPZ being specific for a specific analyte to be detected in each of said SPZs.]

[10. A device as claimed in claim 1, wherein said layer includes a chromotographing section in at least a portion of said substantially planar zones, and further including a sample application zone laminated onto at least a portion of said chromatographing section and in adsorptive contact therewith.]

[11. A device as claimed in claim 1, wherein said layer includes a chromotographing section in at least a portion of said substantially planar zones, and further including a reagent zone laminated onto at least a portion of said chromotographing section and in adsorptive contact therewith, wherein at least some of the reagents required for the detection of the labelling are present in said reagent zone.]

[12. A process for the detection or determination of a component in a fluid wherein said component is an analyte with bioaffinity binding properties by rehydrating or solvating reactants and reagents by the fluid containing the analyte or by an additional fluid, said reactants and reagents being present in a dehydrated state in an analytical device for the detection or determination of a component in a fluid wherein said component is an analyte with bioaffinity binding properties, comprising a layer of a plurality of substantially planar zones adjacent one another and in absorbent contact with one another, aid layer including:

a mobile phase application zone (MPAZ), an intermediate zone (IZ) and an adsorption zone (AZ), liquid being capable of moving by adsorption from said MPAZ through said IZ to said AZ, and wherein said IZ further comprises a solid phase zone (SPZ) having at least one unlabelled reactant, capable of interactions of biological affinity with at least one analyte;

at least one unattached, labelled reactant (conjugate), capable of interactions of biological affinity with said at least one analyte, disposed in an area between the MPAZ and the SPZ; and

an analyte application zone disposed at said MPA or in between said MPAZ and said AZ,

said process comprising:

applying a sample to said analyte application zone, reacting the at least one analyte in the sample in said layer and detecting said at least one analyte in said layer.]

[13. The process as claimed in claim 12, wherein, after the liquid sample containing the analyte has been fed to the MPAZ or after the sample has been fed to a sample application zone and a mobile phase has been fed to the MPAZ, the liquid reaches the end of the AZ, under the control of capillary forces, and reactions between reactants contained in the device and the analyte are thereby set in operation, and, after the labelled reactants which are not attached to the solid phase have been removed chromatographically, the amount of the labelling in the solid phase zone, which is a measure of the analyte concentration in the sample, is determined.]

[14. The process as claimed in claim 12, wherein the reactions taking place in the device are based on the principals of at least one of immunological detection reactions, competitive immunometric or sandwich immunoassay, indirect antibody detection by means of a labelled antibody and antibody detection by means of a labelled antigen.]

[15. The process as claimed in claim 12, wherein said detecting includes using a fluorophor as a labelling

agent which is detected or measured directly or is detected or measured after the addition of a reagent present in the device, or a fluorophor which is detected or measured directly or after the addition of a further reagent is formed from the labelling agent by the addition of a reagent present in the device.

16. The process as in claim 12, wherein said detecting includes using a compound which can be excited to give chemiluminescence as a labelling agent, the chemiluminescence being detectable or measurable after the addition of a reagent present in the device.

17. The process as claimed in claim 12, wherein said detecting includes using an enzyme as a labelling agent, the activity of which is determined with the aid of a reagent present in the device.

18. An analytical device for the detection or determination of a component in a fluid wherein said component is an analyte with bioaffinity binding properties, comprising a layer of a plurality of sheet-like zones adjacent one another and in absorbant contact with one another, said layer including:

a mobile phase application zone (MPAZ), an intermediate zone (IZ) and an adsorption zone (AZ), liquid being capable of moving by adsorption from said MPAZ through said IZ to said AZ, and wherein said IZ further comprises a solid phase zone (SPZ) capable of having at least one unlabelled reactant fixed thereto which is capable of interactions of bioaffinity with at least one analyte, during analysis said at least one unlabelled reactant being fixed to at least one second reactant which is fixed to said solid phase zone;

at least one unattached labelled reactant (conjugate), capable of interactions of biological affinity with said at least one analyte, disposed in an area between said MPAZ and said SPZ; and

an analyte application zone disposed at said MPAZ or in between said MPAZ and said AZ, wherein after application of said at least one analyte, said at least one analyte is reacted with said reactants in said layer and is detected in said layer.

19. A device as claimed in claim 18, wherein said at least one second reactant is fixed to said SPZ by means of covalent bonds.

20. A device as claimed in claim 18, wherein said at least one second reactant is fixed to said SPZ by means of adsorption.

21. A device as claimed in claim 18, wherein said at least one second reactant is fixed to said SPZ by means of an interaction of biological affinity.

22. A device as claimed in claim 18, further including a plurality of solid phase zones (SPZs) for the detection of a plurality of analytes, said analytes including at least one attachment point of biological affinity, each of said SPZs being adjacent one another in said layer and each of said SPZs including said unlabelled reactants fixed thereto, said unlabelled reactants of each SPZ being specific for a specific analyte to be detected in each of said SPZs.

23. A device as claimed in claim 18, wherein the MPAZ has the function of a volume metering element and releases to the subsequent zones at least sufficient liquid for the liquid, controlled by capillary forces, to reach the end of the AZ.

24. A device as claimed in claim 18, wherein the MPAZ is a plastic sponge or a particulate layer which is composed of hydrophilic polymers and which is capable of containing chemicals, buffer substances or other substances required for certain tests.

25. A device as claimed in claim 18, wherein the analyte application zone retains blood cells.

26. A device as claimed in claim 18, wherein said layer includes a chromotographing section in at least a portion of said substantially planar zones; and further including a sample application zone laminated onto at least a portion of said chromatographing section and in adsorptive contact therewith.

27. A device as claimed in claim 18, wherein all or some of the reagents required for the detection of the labelling are present in one or more of the substantially planar zones of the device.

28. A device as claimed in claim 18, wherein said layer includes a chromotographing section in at least a portion of said substantially planar zones, and further including a reagent zone laminated onto at least a portion of said chromotographing section and in adsorptive contact therewith, wherein at least some of the reagents required for the detection of the labelling are present in said reagent zone.

29. A process for the detection or determination of a component in a fluid as an analyte with bioaffinity binding properties by rehydrating or solvating reactants and reagents by the fluid containing the analyte or by an additional fluid, said reactants and reagents being present in a dehydrated state in an analytical device for the detection or determination of the analyte, said device including a layer of a plurality of substantially planar zones adjacent one another and in absorbent contact with one another, said layer including:

a mobile phase application zone (MPAZ), an intermediate zone (IZ) and an adsorption zone (AZ), liquid being capable of moving by adsorption from said MPAZ through said IZ to said AZ;

a solid phase zone (SPZ) in said IZ capable of having at least one unlabelled reactant fixed thereto which is capable of interactions of bioaffinity with at least one analyte, during analysis said at least one unlabelled reactant being fixed to at least one second reactant which is fixed to said solid phase zone;

at least one unattached labelled reactant (conjugate), capable of interactions of biological affinity with said at least one analyte, disposed in a zone between the MPAZ and the SPZ; and

an analyte application zone disposed at said MPAZ or in between said MPAZ and said AZ;

said process comprising:

applying a sample to said analyte application zone, reacting the at least one analyte in the sample in said layer and detecting said at least one analyte in said layer.

30. The process as claimed in claim 29, wherein, after the liquid sample containing the analyte has been fed to the MPAZ or after the sample has been fed to a sample application zone and a mobile phase has been fed to the MPAZ, the liquid reaches the end of the AZ, under the control of capillary forces, and reactions between reactants contained in the device and the analyte are thereby set in operation, and, after the labelled reactants which are not attached to the solid phase have been removed chromatographically, the amount of the labelling in the solid phase zone, which is a measure of the analyte concentration in the sample, is determined.

31. The process as claimed in claim 29, wherein the reactions taking place in the device are based on the principals of at least one of immunological detection

reactions, competitive immunometric or sandwich immunoassay, indirect antibody detection by means of a labelled antibody and antibody detection by means of a labelled antigen.]

[32. The process as claimed in claim 29, wherein said detecting includes using a fluorophor as a labelling agent which is detected or measured directly or is detected or measured after the addition of a reagent present in the device, or a fluorophor which is detected or measured directly or after the addition of a further reagent is formed from the labelling agent by the addition of a reagent present in the device.]

[33. The process as in claim 29, wherein said detecting includes using a compound which can be excited to give chemiluminescence as a labelling agent, the chemiluminescence being detectable or measurable after the addition of a reagent present in the device.]

[34. The process as claimed in claim 29, wherein said detecting includes using an enzyme as a labelling agent, the activity of which is determined with the aid of a reagent present in the device.]

* * * * *

Please add the following claims 35-57:

35. An analytical device for the detection or determination of a component in a fluid wherein said component is an analyte with bioaffinity binding properties, comprising a layer of a plurality of substantially planar zones adjacent one another and in absorbent contact with one another, said layer including:

a mobile phase application zone (MPAZ), a single intermediate zone (IZ) and an adsorption zone (AZ), liquid being capable of moving by adsorption from said MPAZ through said IZ to said AZ, and wherein said IZ comprises a single solid phase zone (SPZ) having at least one unlabelled reactant, capable of interactions of biological affinity with an analyte;

at least one unattached, labelled reactant (conjugate) capable of interactions of biological affinity with said analyte disposed in an area between the MPAZ and the SPZ; and

an analyte application zone disposed at said MPAZ or in between said MPAZ and said AZ, and

wherein all reactants necessary for the immunoassay are present in a dehydrated form in the device, and

wherein after application of said analyte, said analyte is reacted with said reactants in said layer and the presence or amount of the analyte is evaluated optically in the single SPZ.

36. The device of claim 35, wherein the analyte is an antigen and the unlabelled reactant and the labelled reactant are antibodies.

37. The device of claim 35, wherein the analyte is an antibody and the unlabelled reactant and the labelled reactant are antigens.

38. The device of claim 35, wherein the analyte is an antigen and the unlabelled reactant is an antibody and the labelled reactant is an antigen.

39. The device of claim 35, wherein the analyte is an antibody and the unlabelled reactant is an antigen and the labelled reactant is an antibody.

40. The device of claim 35, wherein the analyte is a protein and the unlabelled reactant and the labelled reactant are antibodies.

41. The device of claim 35, wherein the analyte is hCG and the unlabelled reactant and the labelled reactant are antibodies specific for hCG.

42. The device of claim 35, wherein the unattached labelled reactant is labelled directly or indirectly with an enzyme.

43. The device of claim 35, wherein the MPAZ has dimensions to contain sufficient fluid sample to permit the fluid sample to migrate to the AZ.

44. The device of claim 35, wherein said layer of substantially planar zones contains at least two sheet-like strips made from different materials forming a chromathographic analytical device.

45. The device of claim 35, wherein the presence or the amount of the analyte can be evaluated in less than 30 minutes.

46. The device of claim 35, wherein the analyte in the fluid sample can be detected in concentrations as low as 0.3 ng/ml.

47. The device of claim 46, wherein the analyte is hCG.

48. The device of claim 35, wherein the presence of the analyte is detected.

49. The device of claim 35, wherein the amount of the analyte is determined by means of an instrument.

50. The analytical device of claim 35, wherein the AZ is an area where excess unattached, labelled second antibody is removed from the single SPZ.

51. An analytical device for the detection of beta-hCG in a fluid sample by means of a sandwich immunoassay comprising a layer of a plurality of substantially planar zones adjacent one another and in absorbent contact with one another, said layer including:

a mobile phase application zone (MPAZ), a single intermediate zone (IZ) and an absorption zone (AZ), liquid being capable of moving by absorption from said MPAZ through said IZ to said AZ, and wherein said IZ further comprises a single solid phase zone (SPZ) having at least one unlabelled antibody, capable of an immunological interaction with beta-hCG;

at least one unattached labelled antibody (conjugate), capable of an immunological interaction with beta-hCG, disposed in an area between the MPAZ and the SPZ; and

an analyte application zone disposed at said MPAZ or in between said MPAZ and said AZ,

wherein after application of said fluid sample, the presence of beta-hCG is detected visually in the single SPZ.

52. The analytical device of claim 51, wherein the MPAZ has dimensions to contain sufficient fluid sample to permit the fluid sample to migrate to the end of the AZ.

53. The analytical device of claim 51, wherein antigen in the fluid sample can be detected in concentrations as low as 0.3 ng/ml.

54. The analytical device of claim 51, wherein the second antibody is labelled with an enzyme.

55. The analytical device of claim 51, wherein said layer of substantially planar zones contains at least two sheet-like strips made from different materials forming a chromatographic analytical device.

56. The analytical device of claim 51, wherein the immunoassay is to be completed in less than 30 minutes.

57. The analytical device of claim 51, wherein the AZ is an area where excess unattached, labelled second antibody is removed from the single SPZ.